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EXAMINER PATTERSON, K

ART UNIT 2857	PAPER NUMBER
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DATE MAILED: 04/02/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/911,588

Applicant(s)

Malin, Et. Al

Examiner
Kendrick P. PattersonGroup Art Unit
2857☒ Responsive to communication(s) filed on 14 Aug 1997☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-47 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-47 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☒ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5☐ Interview Summary, PTO-413☒ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Specification

1.

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a). The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Reference to a "Microfiche Appendix": See 37 CFR 1.96(c) and MPEP § 608.05. The total number of microfiche and the total number frames should be specified.
- (e) Background of the Invention: The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be

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treated briefly and only to the extent that they contribute to an understanding of the invention.

- (g) Brief Description of the Several Views of the Drawing(s): A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention." Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet. (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps.
- (j) Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less on a separate sheet following the claims.
- (k) Drawings: See 37 CFR 1.81, 1.83-1.85, and MPEP § 608.02.
- (l) Sequence Listing: See 37 CFR 1.821-1.825.

2. This application contains a computer program listing of no more than ten (10) pages. Applicant is reminded that, in accordance with 37 CFR 1.96(b), a computer program listing contained on ten (10) pages or less, must be submitted either as drawings or as part of the specification. If the listing is submitted as part of the specification, it must appear *after* the detailed description of the invention but before the claims and must be in the form of direct

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printouts from a computer's printer with dark solid black letters not less than 0.21 cm. high, on white, unshaded and unlined paper. The sheets should be submitted in a protective cover. See 37 CFR 1.96(b)(2).

Claim Objections

3. Claim 30 is objected to because of the following informalities: "aid basis set" and "solutio" are deemed to be typographical errors. Appropriate correction or clarification is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 11 recites the limitation "said signal" in 4, but does not identify which of the two preceding signals is intended. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 36-47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention recites data embodied on a computer-

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readable medium (i.e., "basis set"). However the data does not impart functionality to either the data as claimed or to the computer. As such, the claimed invention recites non-functional descriptive material, i.e., mere data. Non-functional descriptive material stored on a computer-readable medium is merely carried on the medium, it is not structurally and functionally interrelated to the medium. The allowance of such a claim would exalt form over substance. See MPEP § 2106.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1-9, 11-14, 17, 19, 22-32, 34-37, 40, 42 and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Khalil, et. al. (US 5,747,806).

Concerning applicant's Claims 1, 19, 22, 24, 42 and 45, Khalil, et. al. discloses a method/apparatus for determining the concentration of a target analyte in a (liquid) sample using multi-spectral analysis, comprising:

- a. generating at least one basis set that includes at least one interfering component (Column 6, line(s) 55-61);
- b. applying a spectroscopic signal representative of said sample to said basis set (Column 6, line(s) 62-67);
- c. wherein a component of said sample corresponding to said analyte is identified (Column 7, line(s) 1-5).

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Concerning applicant's Claims 2 and 25, Khalil, et. al. discloses said sample is serum and said basis set comprising interfering components that include any of water, temperature/hydrogen effects, bonding effects, albumin, globin, protein, triglycerides, cholesterol, urea, scatter correction, refractive index correction, depth of penetration and organic, body and physical components (Column 7, line(s) 25-33; & Column 11, line(s) 27-36). Concerning applicant's Claims 3-7, 13, 23, 26-30 and 46, Khalil, et. al. discloses the basis set excludes non-interfering components, and the steps of identifying/extracting interfering components, and comparing the spectra and determining the interactions of the interfering components (Column 7, line(s) 25-36). Concerning applicant's Claims 8, 14 and 31, Khalil, et. al. discloses the basis set is sequentially and iteratively generated for each interfering component (Column 7, line(s) 30-36). Concerning applicant's Claims 9, 17, 32 and 40, Khalil, et. al. discloses characterizing each interfering component and subtracting each from spectra produced at frequency of interest (Column 7, line(s) 18-30; & Column 7, line(s) 59-65). Concerning applicant's Claims 11 and 34, Khalil, et. al. discloses applying multivariate analysis to the signal (Column 7, line(s) 40-43). Concerning applicant's Claims 12 and 35, Khalil, et. al. discloses the multivariate analysis comprises a partial least square analysis, followed by a principal components analysis (Column 7, line(s) 5-15). Concerning applicant's Claims 36-37, Khalil, et. al. discloses a basis set comprising spectral information representative of a target analyte (Column 11, line(s) 26-33); spectral information representative of interfering components (Column 7, line(s) 20-36); in which interfering spectral information is removed (Column 7, line(s) 60-65); and the basis set is stored in memory for multi-spectral analysis by a processor (Column 10, line(s) 16-22). Concerning applicant's Claim 47, Khalil, et. al. discloses the spectral information is non-invasively collected (Column 4, line(s) 49-54).

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Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 10, 15-16, 18, 33, 38-39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khalil, et. al. in view of Bentsen (US 5,518,694).

Concerning applicant's Claims 10, 15-16, 18, 33, 39 and 41, Khalil, et. al. discloses the claimed multi-spectral method/apparatus for determining the concentration of a target analyte, wherein (digital) transform data and basis set are stored in a memory means (Column 10, line(s) 16-22), and a physical model corrects for interfering physical factors including any of scattering, pathlength and temperature (Column 8, line(s) 5-10, 25-30, 40-47 and 60-64).

Concerning applicant's Claim 38, Khalil, et. al. discloses a spectroscopic device (Column 9, line(s) 12-39) and A/D converter (Column 10, line(s) 18-20). However Khalil, et. al. does not disclose expressly the memory means is a look up table (LUT).

Bentsen discloses a system for measuring the concentration of a target analyte, wherein the processing system stores a set of transforms and basis set in a LUT for use during analysis (Column 12, line(s) 47-49). Khalil, et. al. and Bentsen are analogous art because they are from the same field of endeavor, i.e. chemical quantitative analysis. At the time of invention, it would have been obvious to a person of ordinary skill in the art to use the LUT of Bentsen in the spectral analysis system of Khalil, et. al. The reason, suggestion or motivation for doing so would have been to accurately and efficiently store sets of data to quickly retrieved during the analysis process. Therefore it would have been obvious to combine Bentsen with Khalil, et. al. to obtain the invention as specified in Claims 10, 15-16, 18, 33, 38-39 and 41.

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13. Claims 20-21 and 43-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khalil, et. al. in view of Robinson (US 5,830,132).

Concerning applicant's Claims 20-21 and 43-44, Khalil, et. al. discloses the selecting of different wavelengths over three regions (Column 7, line(s) 18-25), but Khalil, et. al. does not disclose expressly the selection of pathlengths.

Robinson discloses a system for measuring the concentration of a target analyte, wherein the claimed optimum pathlengths are selected for three regions (Column 14, line(s) 40-50). Khalil, et. al. and Robinson are analogous art because they are from the same field of endeavor, i.e. chemical quantitative analysis. At the time of invention, it would have been obvious to a person of ordinary skill in the art to use the optimum pathlengths of Robinson in the spectral analysis system of Khalil, et. al. The reason, suggestion or motivation for doing so would have been to accurately and efficiently select the appropriate pathlength due to the differences in absorbance of the interferant (See Robinson at Column 4, line(s) 25-30). Therefore it would have been obvious to combine Robinson with Khalil, et. al. to obtain the invention as specified in Claims 20-21 and 43-44.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Caro (US 5,348,002) discloses a-system for multi-spectral analysis to determine the concentration of a target analyte. Burns, et. al. (US 5,876,121) discloses system of measuring the concentration of an analyte and correcting the measurement of scattering and temperature.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ken Patterson whose telephone number is (703) 305-0650. The examiner can normally be reached on Monday-Thursday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

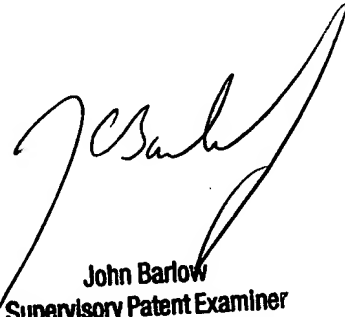
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow, can be reached on (703) 308-3126. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7382.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4900.

kpp

March 25, 1999



John Barlow
Supervisory Patent Examiner
Technology Center 2800